

# Development of a chart that can be used to aid prediction of hidden cancerous growths in colorectal cancer patients before surgery

<b>Submission date</b> 08/03/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/03/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/02/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Bowel cancer is a general term for cancer that begins in the large bowel. Depending on where the cancer starts, bowel cancer is sometimes called colon or rectal cancer.

Early diagnosis of cancer spreading to the lining of the abdomen (peritoneal metastasis (PM)) is crucial to optimal treatment selection and improvement of survival, but it remains a challenge due to the high rate of missed diagnosis on computed tomography (CT) images. The aim of this study was to develop a chart for the identification of PM status in colorectal cancer (CRC) patients.

### Who can participate?

Patients undergoing surgery for colorectal cancer.

### What does the study involve?

Patient records of enhanced CT and laparoscopic exploration from 30/08/2007 to 26/09/2019 were analysed.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

The Sixth Affiliated Hospital, Sun Yat-sen University (China)

### When is the study starting and how long is it expected to run for?

June 2020 to June 2021

### Who is funding the study?

This study was sponsored by the National Natural Science Foundation of China (grant No. 82103084) and the Sun Yat-sen University Clinical Research 5010 Program (grant No. 2019021).

Who is the main contact?

Hui Wang, wang89@mail.sysu.edu.cn

Huaiming Wang, wanghm7@mail.sysu.edu.cn

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Yuanxin Zhang

### ORCID ID

<https://orcid.org/0000-0002-9761-7933>

### Contact details

No.26 Yuancun Road

Tianhe District

Guangzhou

China

510655

+86 17665066505

zhangyx295@mail2.sysu.edu.cn

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Predicting preoperative occult peritoneal metastasis in colorectal cancer patients: Development and external validation of a nomogram and study of its utility

### Acronym

OPM

### Study objectives

Early diagnosis of peritoneal metastasis (PM) is crucial to optimal treatment selection and improvement of prognosis, but it remains a challenge due to the high rate of missed diagnosis on computed tomography (CT) images. The aim of this study was to develop a nomogram for identification of preoperative occult PM status in colorectal cancer (CRC) patients, which can serve as a potential decision-making support tool and guide individualized care.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 17/06/2020, China Research Ethics Committee (Yuancun street, Guangzhou, Guangdong 510515, China; lunli66@126.com; +44 20-38379764), ref: 2020ZSLYEC-109

## **Study design**

Observational longitudinal case-control study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Predicting preoperative occult peritoneal metastasis in colorectal cancer patients

## **Interventions**

All enrolled patients were initially diagnosed as PM-negative by CT readings, but later confirmed with the actual PM status during the laparoscopic exploration. The patients were divided into two cohorts: one training cohort (n = 552 from center 1) and one external validation cohort (n = 70 from center 2).

All enrolled patients underwent enhanced CT examinations within two weeks before operation. The total duration of observation was from the diagnosis to the postoperative histological confirmation. The total duration of follow-up was not applicable because this study aimed to develop a risk model rather than a prognostic model.

## **Intervention Type**

Other

## **Primary outcome(s)**

The actual PM status confirmed using the intraoperative or postoperative histological evaluations at a single time point

## **Key secondary outcome(s)**

The predictive accuracy measured using receiver operating characteristic curve and calibration curves at a single time point

## **Completion date**

17/06/2021

# **Eligibility**

## **Key inclusion criteria**

Current inclusion criteria as of 28/03/2022:

1. Patients were diagnosed with CRC by endoscopy-biopsy pathology, combined with CT and/or other examinations
2. Patients had only one malignant primary tumor

3. Patients did not undergo previous resection of the primary tumor
4. Patients underwent both enhanced CT and laparoscopic exploration

Previous inclusion criteria:

1. Diagnosed CRC by endoscopy-biopsy pathology, combined with CT and/or other examination
2. With no other malignant primary tumours
3. With no previous abdominal malignancies or inflammatory diseases
4. With no previous resection of primary tumour
5. With both enhanced CT and laparoscopic exploration.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

662

### **Key exclusion criteria**

Current exclusion criteria as of 28/03/2022:

1. Typical PM signs on CT
2. Other distant metastases
3. Previous inflammatory diseases

Previous exclusion criteria:

1. With typical PM signs on CT
2. With other distant metastases
3. Incomplete or missing information

### **Date of first enrolment**

30/08/2007

### **Date of final enrolment**

26/09/2019

## **Locations**

### **Countries of recruitment**

China

### **Study participating centre**

**The Sixth Affiliated Hospital, Sun Yat-sen University**

No.26 Yuancun Road  
Tianhe District  
Guangzhou  
China  
510655

**Study participating centre****Zhujiang Hospital, Southern Medical University**

No.253 Gongye Road  
Haizhu District  
Guangzhou  
China  
510000

**Sponsor information****Organisation**

The Sixth Affiliated Hospital of Sun Yat-sen University

**Funder(s)****Funder type**

Government

**Funder Name**

National Natural Science Foundation of China

**Alternative Name(s)**

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

China

## Funder Name

Sun Yat-sen University Clinical Research 5010 Program

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

zhangyx295@mail2.sysu.edu.cn

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		13/07/2022	02/08/2022	Yes	No